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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,720

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EXAMINER

SZPIRA, JULIE ANN

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,720	Applicant(s) KOYAMA ET AL.	
	Examiner JULIE A. SZPIRA	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 9/10/2008.

Claims 1-10 are pending and an action on the merits is as follows.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-7** are rejected under 35 U.S.C. 102(b) as being anticipated by **Fukuda et al. (US 3,871,358)**.

Regarding claim 1, Fukuda et al. discloses a tubular member (4) having an inner passageway (1a) between its opposite ends, a reinforcement member (3) formed by a plate extending along a perimeter of the inner passageway, wherein the tubular member and reinforcement element have curved (flexible) shapes (Figure 3, element 1) and is conformable (has the ability to conform; flexible) to the shape of a pharynx of a human body (column 1, lines 37-41)

The limitation “when guiding to the pharynx and retained there...” has not been given patentable weight, as it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647.

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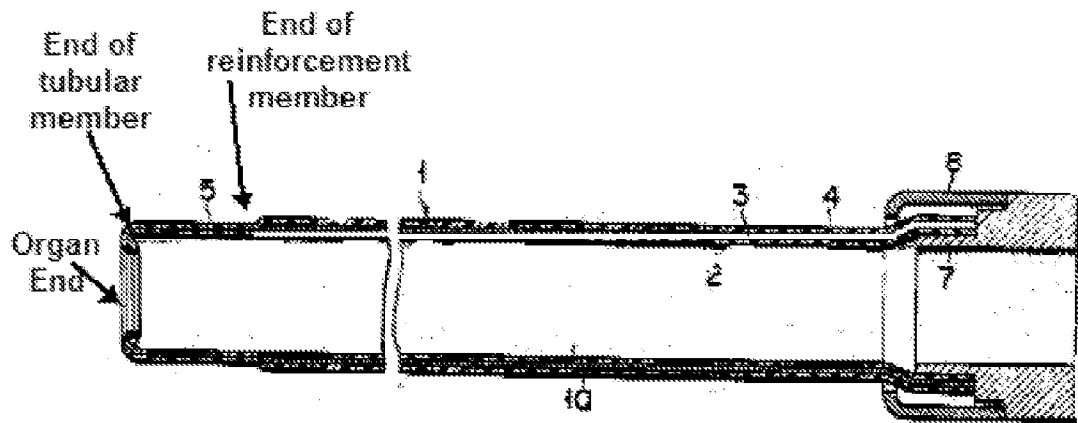
Regarding claims 2 and 3, Fukuda et al. discloses a tubular member (4) having an inner passageway (1a) between its opposite ends, a reinforcement member (3) formed by a plate extending along a perimeter of the inner passageway (column 2, lines 5-9), wherein the tubular member and reinforcement element have curved (flexible) shapes (Figure 3, element 1), and a guiding member (endoscope; 13) with a diameter small enough to allow for a tubular member to be inserted over it (column 2, lines 62-64)

The limitation “when guiding to the pharynx and retained there...” has not been given patentable weight, as it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647.

Regarding claim 4, Fukuda et al. discloses the reinforcement member has the shape of a spiral (helical) continuously extending in a center line direction of the inner passageway (column 2, lines 6-9).

Regarding claim 5, Fukuda et al. discloses wherein a digestive organ end of the tubular member extend toward a digestive organ ahead of a digestive organ end of the reinforcement member (column 2, lines 14-20)

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Regarding claim 6, Fukuda et al. discloses wherein the digestive organ end of the tubular member is slanted with respect to the center line of the inner passageway (Figure 4; column 3, lines 28-31).

Regarding claim 7, Fukuda et al. discloses the tubular member is molded with the reinforcement member buried therein (column 3, lines 44-47 and column 4, lines 1-4)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 8 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Fukuda et al. (US 3,871,358)** in view of **Turnbull (US 5,996,582)**.

Regarding claim 8, Fukuda et al. discloses the invention substantially as claimed above, but fails to disclose the guiding member and tubular member having engagement sections.

However, Turnbull teaches a guide member (shield, 20) with an engagement section (stop, 22), and a tubular member (10), with an engagement section (machine end, 13) for engaging with the guide member engagement section when the guide member is inserted up to a predetermined portion in the inner passageway of the tubular member (column 2, lines 50-56)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include engagement sections to limit the extent of insertion of the guide member in the tubular member (column 2, lines 51-53)

Regarding claim 10, Fukuda et al. discloses the tubular member being made of a resin material (column 2, lines 1-2), but fails to disclose a guiding member made of another resin material harder than the material of the tubular member.

However, Turnbull discloses a stiff rod guiding member made of fiberglass (which is known to contain a resin) (column 2, lines 50-54).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the guiding member out of a harder resin since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

8. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Fukuda et al. (US 3,871,358)** in view of **Gomez (US 6,053,166)**.

Regarding claim 9, Fukuda et al. in view of Christopher discloses the invention substantially as claimed above, but fails to disclose the guiding member and tubular member having alignment marks.

However, Gomez teaches an alignment marks (introduction segments; 22, 26, 30) coupled to the guiding member and tubular member to align (curve) both of the members (column 7, lines 60-64).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include alignment elements so the guiding member and the tubular member achieve the correct position for accurate deployment in the patient (column 8, lines 17-24).

Response to Arguments

6. Applicant's arguments filed 9/10/2008 have been fully considered but they are not persuasive.

7. In response to applicant's argument that the tubular member is "configured to guide the medical instrument into a digestive organ from an oral cavity through a pharynx", is a recitation of the intended use of the claimed

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invention and must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In this case, the device disclosed by Fukuda et al. is capable of being inserted in an oral cavity, and also capable of achieving a curved shape to conform to the shape of a pharynx. The disclosed use of the device does not further define the applicant's device from the cited prior art, as the invention disclosed by Fukuda et al. contains all the structural limitations claimed by the prior art.

Regarding the argument that the device of Fukuda does not have the diameter or strength to be utilized within a pharynx, the device disclosed by Fukuda is capable of being utilized within the pharynx of an infant, or in the pharynx of an injured person where the diameter and the strength of the muscles are reduced.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

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action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Julie A Szpira/
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731